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NIXON & VANDERHYE, PC			BLIZZARD, CHRISTOPHER JAMES	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,479	<b>Applicant(s)</b> MCAULIFFE ET AL.
	<b>Examiner</b> CHRISTOPHER BLIZZARD	<b>Art Unit</b> 3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on **4/14/09**.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) **1-27** is/are pending in the application.

4a) Of the above claim(s) **26** is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) **1-25 and 27** is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on **14 April 2009** is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-166/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. This office action is in response to amendment filed 4/14/09. As directed claims 1, 2 and 16 were amended, claims 17-27 added and no claims cancelled. Therefore this application currently has claims 1-27 pending.

***Election/Restrictions***

2. Newly submitted claim 26 is directed to a species that is independent or distinct from the species originally claimed for the following reasons: figures 5-8 show species 1, and figure 10 shows species 2.

Since applicant has received an action on the merits for the originally presented species 1, this species has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 26 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Drawings***

3. The drawings were received on 4/14/09. These drawings are not acceptable. It is unclear what structure is being referenced as the "anti-asphyxia valve"

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "anti-asphyxia valve" and "gas washout vent" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

5. The amendment filed 4/14/09 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "gas washout valve".

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. What is the structure of the gas washout vent referenced in claim 1, line 8, and where is it located? What is the purpose and the structure of the calibration cap found in claims 7 and 8?

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-6, 9-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choksi (4,360,018), Barnett (5,647,357) and Serowski (5,937,851).

10. Regarding claim 1, Choksi disclose a patient interface mask assembly (fig. 5) in communication with a source of pressurized gas (43) and having a filter assembly (40) configured to receive gas exhaled by the patient in use and to vent exhaust to the atmosphere in proximity to the patient interface (fig. 5). Choksi does not disclose the patient interface is a full face mask with a pressure chamber, shell and cushion that is adjacent to a gas washout vent that will vent gas supplied to the mask in the administration of continuous positive airway pressure therapy. Barnett teaches a face mask (column 1, lines 11-12) with a shell (12) and cushion (18) portion forming a

pressure chamber (column 4, lines 31-34). Serowski teaches a mask (16) (fig. 1, like the one taught by Barnett (fig. 1), for use with a positive pressure air supply (abstract) and is attached with a gas washout vent (100). It would have been obvious to one of ordinary skill in the art to provide the patient interface with filter assembly of Choksi with a mask and gas washout vent for use with a positive pressure air supply as taught by Barnett and Serowski in order to provide the advantage of a better mask seal that will not leak due to being over pressurized.

11. Regarding claim 2, Choksi discloses a mask assembly comprising a connection joint (41) (fig. 5) defining a passage between the patient interface and the vent assembly.

12. Regarding claim 3, Choksi discloses the claimed invention except for the connection joint comprising a T-shaped joint. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the connection joint as a T-shaped joint instead of a Y-shaped joint as taught by Choksi, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

13. Regarding claim 4, Choksi discloses an embodiment of a patient interface assembly wherein the connection joint (3) is an L-shaped joint in which the filter assembly (4) is positioned in use between the source of pressurized gas (14) and the L-shaped joint (fig. 1).

14. Regarding claim 5, Choksi discloses a mask assembly wherein the filter assembly (4) includes an inlet to receive the gas exhausted by the patient, a central chamber (33, 34), a filter (26) provided in the central chamber, and an outlet configured to release the exhausted gas following filtering (column 3, lines 49-57).
15. Regarding claim 6, Choksi discloses a mask assembly wherein the filter is made of a hydrophobic material (column 4, line 45).
16. Regarding claim 9, the combination of Choksi, Barnett and Serowski teach the claimed invention, wherein the swivel exhaust (100) acts as an in-line vent positioned between the pressurized gas and the patient interface (fig. 1b).
17. Regarding claim 10, Choksi disclose a mask assembly wherein the filter assembly (4) includes a filter (26).
18. Regarding claim 11, Choksi discloses a mask wherein the filter has an efficiency of greater than 99.999% (column 3, lines 60-61) but does not disclose the filter having a viral efficiency of greater than 99.999%. However, given the use of the filter is to protect against cross-contamination between patients it would have been obvious to one of ordinary skill in the art at the time of the invention that the efficiency would include viral efficiency since viruses are known as a contaminant in respiratory equipment.
19. Regarding claim 13, Choksi discloses a mask wherein the filter assembly (40) is positioned in use between the source of pressurized gas (43) and the patient interface (42) (fig. 5).

20. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choksi (4,360,018), Barnett (5,647,357) and Serowski (5,937,851) as applied to claim 1 above, and further in view of Wallace (6,209,541).

21. Regarding claims 7 and 8, Choksi, Barnett, and Serowski teach the claimed invention except for a calibration cap on the central chamber. Wallace teaches a vent port (24) with an opening (fig. 1c) that is able to be covered and act as a calibration cap (column 3, lines 14-16).

22. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Choksi (4,360,018), Barnett (5,647,357) and Serowski (5,937,851) as applied to claim 1 above, and further in view of Roberts (6,123,076).

23. Regarding claim 12, Choksi, Barnett, and Serowski teach the claimed invention except for the impedance of the filter being about 2.0 cm at about 60 liters per minute. Roberts teaches a filter (100), similar to the one taught by Choksi, with an impedance of about 2.0 cm at 60 liters per minute (column 10, lines 31-32). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the mask of assembly taught by Choksi, Barnett, and Serowski with a filter as taught by Roberts in order to provide the advantage of less labor of breathing for the user.

24. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choksi (4,360,018), Barnett (5,647,357) and Serowski (5,937,851) as applied to claim 1 above, and further in view of Hely (5,896,857).

25. Regarding claims 14-16, Choksi, Barnett, and Serowski teach the claimed invention except for an anti asphyxia valve provided to a filter cap and the vent. Hely

teaches an inline anti asphyxia valve (14). It would have been obvious to one of ordinary skill in the art at the time of the invention to place the anti asphyxia valve Hely between the filter and gas washout vent as taught by Choksi, Barnett, and Serowski in order to provide the advantage of being able to use the device without constant supervision.

26. Claims 17, 19-24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choksi (4,360,018) and Serowski (5,937,851).

27. Regarding claim 17, Choksi disclose a mask assembly (fig. 5) in communication with a source of pressurized gas (43) and having a filter assembly (40) configured to receive gas exhaled by the patient in use and to vent exhaust to the atmosphere. Choksi does not disclose the patient interface is a full face mask and a vent port positioned on or immediately adjacent the filter assembly. Serowski teaches a mask (16) (fig. 1) for use with a positive pressure air supply (abstract) and is attached with a vent port (100). It would have been obvious to one of ordinary skill in the art to provide the patient interface with filter assembly of Choksi with a mask and vent port for use with a positive pressure air supply as taught by Serowski in order to provide the advantage of a large mask seal that will not leak due to being over pressurized.

28. Regarding claim 19-21, the combination of Choksi and Serowski teach the claimed invention wherein Choksi discloses a mask assembly wherein the filter housing assembly (4) includes an inlet to receive the gas exhausted by the patient, a central chamber (33, 34), a filter (26) provided in the central chamber, and an outlet (24) on a wall (28) configured to release the exhausted gas following filtering (fig. 2) (column 3,

lines 49-57) and Serowski teaches the vent port (100) which would be attached to the outlet (24) of Choksi.

29. Regarding claim 22 and 24, the combination of Choksi and Serowski teach the claimed invention wherein Serowski discloses the vent port being an in-line vent (fig. 1b) that is positioned between the patient interface and pressurized gas source.

30. Regarding claim 23, Choksi discloses the mask assembly wherein the filter assembly (40) is provided between the source of pressurized gas (43) and the patient interface (42), such that both incoming and vented gas from the patient is filtered (fig. 5).

31. Regarding claim 27, Choksi discloses that a filter element (18) could be positioned so that only gas exhausted from the patient would be filtered (fig. 1).

32. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Choksi (4,360,018) and Serowski (5,937,851) as applied to claim 17 above, and further in view of Roberts (6,123,076).

33. Regarding claim 18, Choksi and Serowski teach the claimed invention except for the impedance of the filter being about 2.0 cm at about 60 liters per minute. Roberts teaches a filter (100), similar to the one taught by Choksi, with an impedance of about 2.0 cm at 60 liters per minute (column 10, lines 31-32). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the mask of assembly taught by Choksi and Serowski with a filter as taught by Roberts in order to provide the advantage of less labor of breathing for the user.

34. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Choksi (4,360,018) and Serowski (5,937,851) as applied to claim 17 above, and further in view of Barnett (5,647,357).

35. Regarding claim 25, Choksi and Serowski teach the claimed invention except for the mask having a shell and a cushion. Barnett teaches a face mask (column 1, lines 11-12) with a shell (12) and cushion (18). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the mask assembly of Choksi and Serowski with a mask as taught by Barnett in order to provide an airtight seal with the patient.

***Response to Arguments***

36. Applicant's arguments with respect to claim 1-16 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

37. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771

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